K060971

OCT 2 4 2006

EXHIBIT 2
510(k) Summary

1. Submitter Name: OMI Manufacturing Pty Ltd
2. Address: 1/12 Booran Dr.
Slacks Creek, Queensland,
Australia 4127
3. Phone: 61 7 34517000
4. Fax: 61 7 32094765
5. Email: projects@omiltd.com
6. Contact: Graham McNicol Project Manager
7. Establishment Registration Number: 3003462738
8. Date summary prepared: March 1, 2006
9. Device Trade or Proprietary Name: OMI Retractable Safety Syringe
10. Device Common or usual name: Safety Syringe
11. Device Classification Name: Piston Syringe/Syringe Anti-stick
12. Device Classification Code: MEG
13. Device Class: class 11 as per regulation 21 CFR 880.5860
14. Compliance (performance Standard): None established under section 513-514
Complies with voluntary standards and FDA guidance documents:
ISO6009: Hypodermic needles for single use color coding for identification.
ISO7864 Sterile hypodermic needles for single use
ISO7886-1 Sterile Hypodermic syringes for single use
ISO7886-4 Syringes with reuse Prevention Features
ISO10993: Biological evaluation of medical devices
EN550/ISO11135 Sterilization of Medical Devices- Validation and routine control Of Ethylene Oxide Sterilization
15: Predicate Device: Vanishpoint Syringe (K946219) from Retractable Technologies Inc.
16: Device Description: The OMI Retractable Safety Syringe is a Sterile, Non Toxic, Non Pyrogenic, Latex Free, Single Use, automatically activated anti-stick piston syringe with integral needle. Available in 1ml, 3ml, 5ml and 10ml sizes with various needle sizes.
The OMI Retractable Safety Syringe works like a conventional hypodermic syringe except for its ability to retract the contaminated needle inside the plunger immediately after patient injection. Needle retraction is activated by the syringe user.
The primary intended use is to administer safe and accurate subcutaneous and intramuscular injections. The secondary intended use is to retract and contain the contaminated needle after injection for the purpose of aiding in the prevention of accidental needle stick injuries.

17. **Indications for Use:** This device is a safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries. EO sterilized, non-pyrogenic, and latex free.
The function of the OMI Retractable Safety Syringe is to provide a safe, accurate and reliable method of injecting medication into a patient.

18. **Summary Comparing Technological Characteristics With Predicate Devices:**
The OMI Manufacturing Pty Ltd makes a Substantial Equivalence claim of the OMI Retractable Safety Syringe to Retractable Technologies, Inc., Pop-n-Lock Syringe (currently marketed as the Vanishpoint syringe), 510(k) # k946219. Both syringes are similar and in some cases the same, with regards to parts, design, material, operating procedure and intended use.
Both the OMI and Vanishpoint syringes consist of a syringe barrel, syringe plunger, single lumen hypodermic needle, needle hub and stem.
Both have a spring retracting mechanism which is user activated once medication has been injected. Both are plunger syringes which are supplied with permanently attached needles. Both are supplied sterile, single-use and disposable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2006

OMI Manufacturing Pty., Limited
C/O Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K060971
Trade/Device Name: OMI Retractable Safety Syringe and OMI Insulin Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: October 16, 2006
Received: October 19, 2006

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

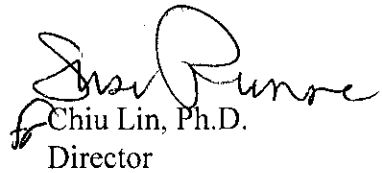
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060971

Device Name: OMI Insulin Safety Syringe

Indications For Use:

The OMI Safety Insulin Syringes are intended for the subcutaneous injection of insulin. In addition, the syringe is designed to aid in prevention of needlestick injuries.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 2

...n of Anesthesiology, General Hospital,
...on Control, Dental Devices

...r K060971

Indications for Use

510(k) Number (if known): K060971

Device Name: OMI Retractable Safety Syringe

Indications For Use:

This device is a safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries. EO sterilized, non-pyrogenic, and latex free.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW 10/25/2006

...n Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices

...Number K060971